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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,399

11/04/2002

Barry L. Stoddard

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7590

11/04/2004

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EXAMINER

SCHNIZER, HOLLY G

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,399

Applicant(s)

STODDARD ET AL.

Examiner

Holly Schnizer

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-15 are pending and have been considered in this Office Action.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

The Brief Description of the Drawings is objected to because it refers to figure 4A and 4B but the drawing does not have a part A or B. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fijnvandraat et al. (Blood (1998) 91(7): 2347-2352).

Fijnvandraat et al. discloses an N-terminal truncated factor VIII lacking 2171 residues (from 2000-2200) of the first N-terminal amino acids of the full-length factor VIII. The Fijnvandraat et al. factor VIII sequence contains residues 2172-2332 of wild-type human factor VIII (see p. 2348, lines 16-17) and has the same sequence as residues 2174-2326 or 2169 to 2332 of SEQ ID NO:1. Thus, Fijnvandraat et al. is considered to meet the limitations of Claims 7, 8, and 10.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al. (Blood (1990) 75(10): 1999-2004).

Foster et al. discloses peptides spanning the C2 domain of factor VIII. Peptides 2138-2152, 2143-2157, 2153-2167, 2158-2172, 2168-2182, 2173-2187, 2183-2197, 2188-2202, and 2198-2212 are all considered to be N-terminal truncated factor VIII lacking 2000 to 2200 of the first N-terminal amino acids of the corresponding full length factor VIII since all of these peptides lack the first 2000 to 2200 amino acids of factor VIII. Thus, Foster et al. is considered to meet the limitations of Claim 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 8, 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 8, and 10 are unclear as to what substitutions are considered "conservative". The term "conservative" substitution is not defined in the present Specification and those of skill in the art may consider it to mean various things such as amino acids with the same polarity or functional equivalents or those that are structurally similar. The Specification provides examples of "conservative substitutions" which even include insertion of cysteine at position 2169 (p. 11, line 2).

Claim Objections

Claim 9 is objected to for depending from a rejected claim.

Conclusions

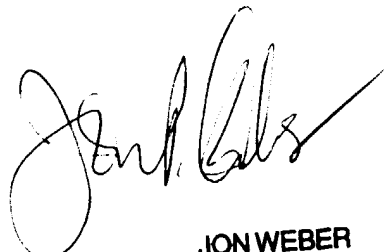
Claims 3, 7, 8, and 10 are rejected. Claim 9 is objected to. Claims 1-2, 4-6, and 11-15 are in condition for allowance. A thorough search of the prior art did not reveal any teaching or suggestion of a crystal of a protein-ligand complex comprising the N-terminal truncated factor VIII of the present claims. Furthermore, there is no teaching or suggestion of an N-terminal truncated factor VIII lacking from 2000-2200 of the first N-terminal amino acids of factor VIII wherein selenomethionine has been substituted for methionine in the sequence. Therefore, Claim 9 would be allowable if written in independent form to include all of the limitations of Claim 7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Holly Schnizer
October 27, 2004


JON WEBER
SUPERVISORY PATENT EXAMINER